MANNATECH

4074 '03 JUN'24 A6:21

June 9, 2003

Office of Special Nutritionals Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway. College Park, MD 20740



Re: Statement of Nutritional Support Notification - Ambrotose AO

Dear Sir or Madam:

In accordance with 21 U.S.C. § 343 (r) and 21 CFR § 101.93, Mannatech Incorporated, 600 S. Royal Lane, Ste 200, Coppell, TX 75019, hereby submits an original and two copies of it's notification within 30 days of first marketing its product with the statements presented below:

Supplement Brand Name: Ambrotose AO

Supplement Ingredients: See attached SF box.

Text of Statements of Nutritional Support:

- 1. Provides antioxidant-rich nutrients to help the body cope with the harmful effects of oxidative stress.
- 2. Provides antioxidant-like activity which can act as free radical scavengers, free radicals are highly reactive substances which may occur in the body and can be by lifestyle factors such as excess dietary fats, cigarette smoke, alcohol consumption, and pollutants or stress.
- 3. Antioxidant-rich formula to help with the harmful effects of toxins, environmental stress, poor diet and daily physical and oxidative stress - all of which cn damage DNA, cells and tisues and lead to premature cellular aging...
- 4. Antioxidant and immune support.
- 5. Studies have shown that antioxidants protect cells from the cell-damaging effects of free radicals.
- 6. Nutritional support for general well being.

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- 7. Supports antioxidant protection.
- 8. An excellent source of antioxidant vitamin E for immune support.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Yours truly,

Dennis R. Sparkman, Ph.D.

Executive Director of Global Regulatory Affairs

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Enclosure: Ambrotose AO SF box.

[Right Panel]

Supplement Facts

	Amount Per Serving	% Daily Value
Vitamin E (as mixed d-alpha-, d-beta, d-delta, and d-gamma tocopherols)	18 IU	60%
"Outback AO" proprietary blend	111 mg	
Quercetin dihydrate		†
Grape skin extract (fruit)		†
Green tea extract (leaves)		†
Australian Bush Plum (Terminalia ferdinand	liana) (fruit)	†
Ambrotose® Phyto Formula	332 mg	
Gum Arabic		†
		†
Xanthan gum		1
Xanthan gum Gum tragacanth		†
Gum tragacanth	pol® powder	†

Other Ingredients: Gelatin.